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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,884	05/31/2001	Thomas Hoeg-Jensen	6213.200-US	1019

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/870,884	<b>Applicant(s)</b> HOEG-JENSEN ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, 21-26, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 17-20 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

A sequence listing was received on April 20, 2005. However, this sequence listing contains only one sequence, whereas there are eighteen numbered sequences in the specification. Applicants state at page 8, third paragraph, of the response that the sequence listing filed April 20, 2005 is an addition to sequence listing filed July 21, 2003. However, there is no provision for this procedure in the rules. As set forth in 37 CFR 1.821(c), each sequence disclosed must appear separately in the sequence listing. Under the format proposed by Applicants, the sequence listing filed July 21, 2003 does not contain a listing for the amino acid sequence at page 23, line 23 - page 24, line 1, of the specification. Further under the format proposed by Applicants, the sequence listing filed April 20, 2005 does not contain a listing for the amino acid sequences previously identified as SEQ ID NOS:1-17. If the format proposed by Applicants were to be followed, the result would be the presence of two different amino acid sequences in the two sequence listings identified as SEQ ID NO:1, and no amino acid sequence identified as SEQ ID NO:18. A single sequence listing including each disclosed sequence is required.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

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2. The amendment filed April 20, 2005 canceling claim 4 is in improper format under 37 CFR 1.121(c)(4)(i) because claim text is presented for the canceled claim.

3. The amendment filed April 20, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation by reference statement in the claim for priority inserted by the amendment is new matter because there was no equivalent statement present in the disclosure at the time the application was filed. See MPEP 201.11(III)(F) and 608.01(p)(I)(B).

Applicant is required to cancel the new matter in the reply to this Office Action.

4. Claim 26 is objected to because of the following informalities: At claim 26, line 2, it is believed that "is" should be changed to "of". Appropriate correction is required.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-16, 21-26, 28, and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 and 31 of copending Application No. 10/307,678. Although the conflicting claims are not identical, they

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are not patentably distinct from each other because the claims of the '678 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by the Jeong et al article (J. Controlled Release, Vol. 1, pages 57-66). The Jeong et al article teaches glycosylated bovine insulin which is bound to Con A inside a microcapsule. Glycosylation sites include the B-29 lysine residue. The glycosylated insulin is displaced from the Con A by glucose in response to, and proportional to, the amount of glucose in the blood. See, e.g., the abstract; page 58, column 2, second full paragraph; Scheme 1; and page 65, column 1, second full paragraph. The saccharide groups used by the Jeong et al article correspond to Applicants' glucose-sensing groups. In view of the similarity in structure and function between the insulin derivatives of the Jeong et al article and Applicants' claimed insulin derivatives, the former are deemed inherently to have the same glucose affinity and to have the same capability of forming water soluble high molecular weight aggregates as the latter, and the saccharide groups of the Jeong et al article are deemed inherently to be capable of effecting the formation of high molecular aggregates to the same extent as Applicants' glucose-sensing groups. Sufficient evidence of similarity is deemed to be present to shift the burden to Applicants to provide evidence that their claimed insulin derivatives are unobviously different than those of the Jeong et al article.

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8. Applicant's arguments filed April 20, 2005 have been fully considered but they are not persuasive.

The provisional obviousness-type double patenting rejection is maintained. Note that claims 5-14 of the '678 application are drawn to insulin modified with a glucose-sensing aryl boronate group. The provisional obviousness-type double patenting rejection can be withdrawn in accordance with the procedures of MPEP 822.01 when the conditions set forth therein are satisfied.

Claim 26 remains rejected over the Jeong et al article. Claim 26 was not amended in Applicants' response (note that claim 26 is not dependent upon claim 1), and Applicants did not submit any arguments as to why claim 26 was novel and unobvious over the applied prior art.

9. Claims 17-20 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

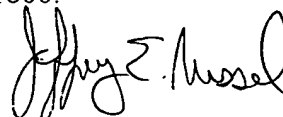
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large, looped "J" and "R".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel

May 17, 2005